

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 7, 2016

Chelsea Moyer Regulatory Affairs Specialist Tender Corporation 944 Industrial Park Road Littleton, NH 03561

Subject: Label Amendment – Addition of marketing claims against Zika virus and other

minor changes

Product Name: BEN'S 100 INSECT REPELLENT

EPA Registration Number: 56575-7 Application Date: 02/04/2016 Decision Number: 513876

Dear Ms. Moyer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

Sincerely,

Jennifer Urbanski Saunders, Product Manager 4 Invertebrate & Vertebrate Branch 1 (IVB1)

Registration Division (7505P) Office of Pesticide Programs

Enclosure

Ben's 100 Insect Repellent

[Tick and Insect Repellent]

Active Ingredient:

*N,N-diethyl-m-toluamide (m-deet) + Related Isomers

ACCEPTED

Mar 07, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 56575-7

["The choice of Adventure Medical Kits (logo)" -Dr. Eric Weiss]

[Repels Insects That May Transmit West Nile Virus [And] [&] Lyme Disease]

[Repels Mosquitoes That May Transmit Zika Virus [Repels Mosquitoes That May Transmit Dengue Fever [Repels Mosquitoes That May Spread [Zika Virus,] [West Nile Virus,] [or] [and] [Dengue Fever]

[MAX FORMULA] [Up to 10 Hours Protection]

[REPELS]

[Mosquitoes, Ticks, Black Flies, Fleas. Biting Midges, Chiggers, Sand Fleas Stable Flies]

[Contains no alcohol. Non-oily]

Keep out of Reach of Children WARNING DO NOT USE ON INFANTS

Not recommended for use on children under the age 10.

See [card] {or} [behind peel back] for additional precautionary statements.

Net Contents ___ Oz. (__ml) [Lotion] {or} {Pump Spray]

Tender Corporation

[944 Industrial Park Road]

{Littleton is a small town and mailing address is sufficient with just zip code}

Littleton, NH 03561

Questions? Call 1-888-258-4696 ext 236

EPA Reg. NO 56575-7

EPA Est. 56575-NH-1

{Container Label-Lotion Back Panel}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read and follow all directions and precautions on [this product label]

{or}[all labels] and packaging {where size requires peel-back or second label}].

Apply a few drops to your palm and wipe on exposed skin areas. Do not apply over cuts, wounds or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put on the child. Use just enough repellent to cover exposed skin. Do not use under clothing. Avoid over-application of this product. Wash hands after applying. After returning indoors, wash treated skin with soap and water. Repeat as needed.

{Container Label-Pump Spray Back Panel}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read and follow all directions and precautions on [this product label]

{or}[all labels and packaging {where size requires peel-back or second label}].

Remove protective cap and spray on all exposed skin areas. Keep nozzle pointed away from face. Do not inhale. Do not apply over cuts, wounds or irritated skin. Do not apply near eyes and mouth. To apply to face, spray on hands and rub on. Apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin. Do not use under clothing. Avoid over-application of this product. After returning indoors, wash treated skin with soap and water. Wash treated clothes before wearing again. Do not spray in enclosed areas. For ticks and chiggers, apply to shoe tops, socks and around openings in clothing. Repeat as needed.

{Container Label continued for-Both Lotion and Pump Spray Back Panel}

Storage and disposal

Storage: Store in a cool dry (preferably locked) storage area in accessible to children and pets and away from heat or open flame. **Disposal:** Do not puncture or incinerate. **If empty:** Do not reuse this container. Place in trash or, if available offer for recycling. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Refer to [card] {or} [behind peel back] for complete Precautionary Statements

{Card Label-Front Panel}

Ben's 100 Insect Repellent	
[Tick and Insect Repellent]	

[Child -Resistant Packaging]

[Repels Insects That May Transmit West Nile Virus And Lyme Disease]

[Repels Mosquitoes That May Transmit Zika Virus
[Repels Mosquitoes That May Transmit Dengue Fever
[Repels Mosquitoes That May Spread [Zika Virus,] [West Nile Virus,] [or] [and] [Dengue Fever]

[MAX FORMULA]
Up to 10 Hours Protection
REPELS:

Mosquitoes, Ticks, Black Flies, Fleas. Biting Midges, Chiggers, Sand Fleas Stable Flies

Net Contents ___ Oz. (___ml) [Lotion] [Pump]

{Card Label- Lotion Back Panel}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read and follow all directions and precautions on [this product label]

{or}[all labels] and packaging {where size requires peel-back or second label}].

Apply a few drops to your palm and wipe on exposed skin areas. Do not apply over cuts, wounds or irritated skin. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put on the child. Use just enough repellent to cover exposed skin. Do not use under clothing. Avoid over-application of this product. Wash hands after applying. After returning indoors, wash treated skin with soap and water. Repeat as needed.

{Card Label-Pump Spray Back Panel}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read and follow all directions and precautions on [this product label]

{or}[all labels] and packaging {where size requires peel-back or second label}].

Remove protective cap and spray on all exposed skin areas. Keep nozzle pointed away from face. Do not inhale. Do not apply over cuts, wounds or irritated skin. Do not apply near eyes and mouth. To apply to face, spray on hands and rub on. Apply sparingly around ears. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin. Do not use under clothing. Avoid over-application of this product. After returning indoors, wash treated skin with soap and water. Wash treated clothes before wearing again. Do not spray in enclosed areas. For ticks and chiggers, apply to shoe tops, socks and around openings in clothing. Repeat as needed.

{Card Label -Both Lotion and Pump Spray Back Panel}

{Back Panel: on 3.5 ounce or smaller size products labeling will always contain complete "back panel" label on attached card (blister card type outer packaging) or on peel-back affixed to immediate (inner container) or both.

Please see Draft Label enclosed as representative of the "3.4 ounce packaging"}

Storage and disposal

Storage: Store in a cool dry (preferably locked) storage area inaccessible to children and pets and away from heat or open flame.

Disposal: Do not puncture or incinerate. **If empty:** Do not reuse this container. Place in trash or, if available offer for recycling. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING: Causes substantial but temporary eye injury. Do not get in eyes. Harmful if swallowed. Use of this product may cause skin reaction in rare cases. If you suspect a reaction to this product, discontinue use, wash skin and call your local poison control center. If you go to the doctor, take this product with you.

FIRST AID STATEMENT

	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
If in Eyes	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center for treatment advice.
	Immediately call a poison control center or doctor for treatment advice.
	Have a person sip a glass of water if able to swallow.
If swallowed	Do not induce vomiting unless told to do so by the poison control center or doctor.
	Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or when going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents) you may call the National Pesticide Information Center at 1-800-858-7378. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

{Note: The First Aid statements' grid format will be used if market label space permits: otherwise a paragraph format will be used}

Physical or Chemical Hazards

Exposure to temperatures above 130°F may cause bursting. Keep off synthetics, plastics, furniture, and painted surfaces. May damage leather.

EPA Reg. NO 56575-7

EPA Est. 56575-NH-1

{February 3, 2016 Label Text for Submission}

{When size does not allow a peel back, product will <u>always be sold attached to a card with complete "back panel" labeling</u> from above and these very small sizes will have the following on the immediate (inner) packaging---Please see Draft Label enclosed as representative of the "very small packaging"}

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read, understand, and follow all directions and precautions on this label and on outer package.

Shake well. [Remove tab] [and twist cap] Keep nozzle pointed away from face. DO NOT: ●spray directly on face ●inhale ●apply over cuts, wounds or irritated skin ●spray in enclosed areas ●apply near eyes or mouth ●apply to children's hands● allow children to handle this product ●use under clothing.

To use on face or children, spray on your own hands first and then apply sparingly and avoid eyes. Use only enough repellent to cover exposed skin. Repeat as needed. Wash hands after use. After returning indoors wash treated skin with soap and water.

Storage and disposal-Read, understand, and follow instructions on outer package

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Read entire WARNINGS and PRECAUTIONS on outer package. Causes substantial but temporary eye injury. Do not get in eyes. Harmful if swallowed. Use of this product may cause skin reaction in rare cases. If any reaction occurs stop use, wash skin and call your local poison control center.

First Aid

If in Eyes Hold eye open and rinse slowly and gently with water for 20 minutes. Remove contact lenses after the first 5 minutes then continue rinsing eye. If swallowed Immediately call a poison control center or doctor for advice. Sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or doctor. Do not put anything in mouth of an unconscious person. Have this label with you when going for treatment. For more information you may call the National Pesticide Information Center at 1-800-858-7378. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Physical or Chemical Hazards Read and understand outer package

[Keep off synthetics, plastics, furniture, and painted surfaces. May damage leather.]

	[] Denotes optional/alternate verbiage
{	} Denotes Language that does not appear on market labeling

{February 3, 2016 Label Text for Submission}

{Everything below is Optional Selling Copy-Lotion, Pump Spray}

Full Strength repellent for maximum protection against ticks and all types of biting insects.

Use Ben's 100 when the bugs are especially intense or when all-day protection is needed. See our complete line of products for the prevention and treatment of outdoor ailments at www.tendercorp.com. Recyclable Packaging Made Primarily from Recycled Fibers. Please Recycle When Possible

A portion of your purchase goes towards Tender's Environmental Donation Program.

For more information, write Tender Corporation. Attn: Jayne

A Product of Tender Corporation 944 Industrial Park Road Littleton, NH 03561 www.tendercorp.com

- Ben's -- Trusted for over 30 years!
- Level {for packages with clear indicator of amount remaining}
- [Running Low] {for packages with clear indicator of amount remaining}
- Now with Twist Close Cap!
- Airplane carry-on size
- Maximum carry-on size
- TSA approved travel size
- TSA travel size
- TSA approved carry-on size
- TSA carry-on size
- Convenient Travel Size
- Convenient Airplane Travel Size
- Airplane Travel Size
- Airplane carry-on
- Maximum Airplane Size
- Max Airplane Travel Sixe
- Approved Airplane Travel Size
- Approved for Airplane Travel
- Approved Airplane Size
- {} Denotes Language that does not appear on market

- Airplane Size
- Carry-on Size
- Max carry-on size
- Maximum Airplane Travel Size
- Max Airplane Size
- Distinctive DEET insect repellent formula that contains NO ALCOHOL.
- {roll on only} Now in a new Roll-on applicator allowing you to apply Ben's 100 exactly where you want it and not on your hands, clothing or gear.
 Great for applying to the face and neck. Just dab on and spread for complete coverage.
- For comfortable outing with the family. Protects against ticks, mosquitoes and [most] [all] types of biting insect.
- For 10 hours of protection.
- Full Strength repellent for maximum protection against ticks and [most] [all] types of biting insects